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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,868

12/09/2003

Ruchika Singhal

1023-330US01

6697

28863 7590 09/18/2008  
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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

09/18/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiplaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,868	<b>Applicant(s)</b> SINGHAL ET AL.	
	<b>Examiner</b> William H. Matthews (Howie)	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,15-17 and 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-18-08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-18-08 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-7,9-12,15-17,24-32 have been considered but are moot in view of the new ground(s) of rejection. Regarding the 112<sup>1st</sup> paragraph rejection of claim 25, Applicant's arguments are persuasive and the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12 and 27 each recite creating a

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recess and placing the device in the recess **in combination** with placing the device in a pocket (see claims 1 and 26). Paragraph 51 only describe an alternative placement method for the device and fails to suggest or explain how a recess could be used in conjunction with the pocket.

Claims 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The combination of placing the device in a pocket **and** recess is not explained in the specification. Furthermore it would not have been readily apparent how a recess could be formed in the pocket (as defined in the specification) such that the device is implanted in both the pocket and recess.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7,9-12,15-17,24-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. USPN 6427086 in view of Berrang et al. USPN 6648914 ("Berrang '914") and Berrang US PUB 2003/0109903 (Berrang '903").

Fischell et al. disclose implanting a low profile medical device between a scalp and cranium at the top of the head (see Figure 23). The device may comprise a neurostimulator with brain leads, may be secured via bone screws, and may be implanted in a recess (see abstract and column 31 lines 60- column 32 line 52). Fischell et al. lacks the express disclosure of the implantation steps (claims 1,11,25-29,31), or the specific dimensions of the device recited in claims 2-6.

Berrang '914 teach implantable devices for placement between the scalp and cranium wherein the device includes a control module divided into two modules covered by a flexible overmold (claim 2), thickness of about 4-8mm (claim 3), and a peripheral edge angle of about 135 degrees (claims 5-6) in order to provide the device with cranium conformable features. The implantation steps include administering local anesthetic (claim 17), making a C-shape incision (claim 31), and creating a pocket behind the incision (figure 3) to place the device in the pocket.

Berrang '903 teach implantable devices for placement between the scalp and cranium wherein the device includes a periphery angle of about 135 degrees and wherein the thickness is about 6 mm, and where a flap/pocket method is used (see figure 1-3 and paragraph 46).

Regarding claim 11, the step of suturing a flap would have been readily apparent to close to the flap incisions taught by each of Berrang '814 and Berrang '903.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method of implantation disclosed in Fischell et al. to include the features and steps of Berrang '914 and Berrang '913 in order to provide a

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low profile, conformable implantation procedure. Furthermore it is well within the level of one of ordinary skill in the art to apply surgical steps known in the art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
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